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EXAMINER	
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ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,556	HOTTEN ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003 and 24 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-32* is/are pending in the application.

4a) Of the above claim(s) *24-29,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 20-23, 30) in Paper No. 13 (5/15/03) is acknowledged. The traversal is on the ground(s) that the Examiner has made a restriction between Groups I and III (claim 28) and Applicants assert that no undue burden would be placed on the Examiner if the two Groups were to be considered in the same application as the searches would be co-extensive. However, the Examiner can only rejoin the groups if the product of Group I is found allowable and if the process of use claims are of the same scope as the allowable product claims.

Furthermore, Applicants request rejoinder of the subject matter of Groups I and III (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product which was free of the prior art. However, only if the product claims of Group I are found allowable, the subject matter of Group I will be rejoined with the process claims of Group III, if the process claims are of the same scope as the allowable product claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-29, 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed i.e. a more specific title that would identify the antibody by the protein it binds to.

2b. Applicant is reminded of the proper content of an abstract of the disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the claimed compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics."

Complete revision of the content of the instant abstract to include the claimed antibodies, is required on a separate sheet.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 20-23, 30, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 20 is clearly a single means claim because it encompasses any antibody to any protein that exists now and in the future, irrespective of the structure of that protein. Furthermore, the claim encompasses any antibody to a fusion protein which is encoded by a DNA which "comprises" the nucleotide sequence set forth in SEQ ID NO:1. Claim 20 is a single means claim because the specification has only provided a description for an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:3 (page 11, first complete para). A

single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712,714 - 715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

Further, the instant specification does not provide an adequate description of the genus of antibody compounds encompassed by this claim. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by

structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. The instant specification does not provide a structural formula which is definitive of a genus of proteins to which the antibody claimed in claim 20 can bind. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot following the guidance presented therein and produce the claimed antibody to the protein of SEQ ID NO:3 without first making a substantial inventive contribution.

3b. Claims 20-23 and 30, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Because of the presence of "encoded by a DNA comprising the nucleotide sequence set forth in SEQ ID NO:1" in claim 20, the instant claims encompass an antibody which binds to an epitope that is not contained within SEQ ID NO:3. It is old and well known in the art that the portion of a protein to which an antibody binds usually consists of no more than six to eight amino acid residues. It was also well known in the art long before the instant invention was made to express a recombinant protein as part of a fusion protein "comprising", in addition to the amino acid sequence of a desired protein, an antigenic tail such as a "FLAG epitope", a polyhistidine tail, or a "Protein A" fragment to facilitate the purification of the desired protein. The instant specification encompasses a polypeptide of amino acid sequence set forth in SEQ ID NO:3 which can include a "tag". Because of the presence of the term "comprising" in the instant claims, they encompass any antibody which can bind to any epitope which can be expressed as a portion of a polypeptide comprising the amino acid sequence as set fourth in SEQ ID NO:3 and, therefore they essentially encompass any antibody which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody which binds to any epitope other than an epitope which is contained within SEQ ID NO:3 of the instant application.

3c. Claims 20-21, 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody to the full-length protein of SEQ ID NO:3,

does not reasonably provide enablement for the mature protein encoded by the nucleotide sequence of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 20, sub-part (c), and claim 30, sub-part (c), encompass the mature, secreted form of the protein of SEQ ID NO:3. The specification does not disclose the specific sequence of the mature protein recited in claim 1. The full-length protein has the sequence of SEQ ID NO:3 as disclosed in the specification, which is not equivalent to the specific mature polypeptides recited in claims 20, 30, sub-parts (c). The skilled artisan cannot envision the detailed chemical structure of the encompassed protein and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The invention is drawn to a protein that occurs naturally since it is encoded by a naturally occurring polynucleotide. The prior art teaches neither the encoded protein nor the recited polynucleotide. It is acknowledged that the skill of the artisan in the molecular biology art is high. It is further acknowledged that in some cases, leader/signal sequences are readily identifiable because of high conservation of certain such sequences across species, families or groups of proteins. Due to the lack of guidance in the prior art and current application, one skilled in the art could not predict if the mature form of the protein differs from the full-length form, and if it does, how. The breadth of the claims comes from encompassing a protein, the form of which is not known, and the possibility that more than a single mature protein exists. As written in the claims, the mature form is described as a single

compound, however, there is precedence in the prior art for full-length unprocessed proteins to be processed into more than one unique compound. It is not known whether this protein has only a single precursor form or whether it goes through several rounds of signal sequence processing to produce several mature forms as is the case with, for example Neurophysin I and II, which are produced form prepropressophysin and prepro-oxyphysin, respectively (Ganong, 1995, page 220, Fig. 14-11) and pro-opiomelanocortin, which is cleaved during processing to form 8 functional peptides (Creighton, 1984, page 71, Fig. 2-6), or cholecytokinin-pancreozymin (CCK), which undergoes multiple processing steps such that prepro-CCK is processed into many fragments (Ganong, 1995, page 446). There are also cases of protein processing in which the mature form differs from the full-length most significantly in the absences of amino acids internal in the protein (see for example Crieghton, 1984, page 72, Fig. 2-7 of chymotrypsinogen A). Therefore, in the instant case one cannot predict what that mature form(s) will be. For these reasons, it does not appear that the inventors were in possession of the claimed invention at the time of filing.

Claim rejections-35 USC § 112, second paragraph

4. Claims 20-23, 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 30 are indefinite in the recitation of the term "essentially the same...activities". This language is vague and indefinite because it is unclear what specifically is being claimed. How much essentially the same does the activity have to be? Therefore, the metes and bounds of the claims are unclear.

Claims 21-23 are rejected as vague and indefinite insofar as they depend on claim 20 for this limitation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by the Hopp et al. patent (5,011,912). As explained above, these claims encompass an antibody which binds to any antigenic peptide, including the flag epitope DYKDDDDK which was bound by the antibody of Hopp et al. prior to the time of the instant invention. The reference discloses the antibody (column 5, lines 55-59) meeting the limitations of claim 20, 22, a hybridoma (column 4, lines 51-68; column 5, lines 1-54), and the monoclonal antibody so produced (column 8, claims 2-4) meeting the limitations of claims 21, 23. Therefore, the antibody and monoclonal antibody of the reference anticipate instant claims 20-23.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hopp et al. in view of the Stratagene catalog (1988, page 39).

The teachings of Hopp et al. have been set forth above in para 5. However, these references do not teach the use of a kit. The Stratagene catalog does teach a motivation to combine reagents of use into a kit (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the antibodies as taught by Hopp et al. into a kit as taught by Stratagene since the Stratagene catalog teaches a motivation for combining reagents of use in any assay into a kit. It states that "Each kit provides two services: 1) a variety of different regents have been assembled and premixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 1 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1)

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
October 1, 2003